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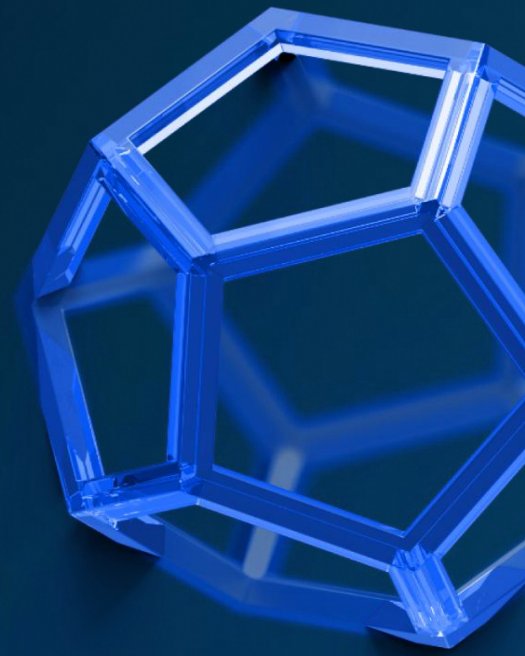
Market Access for Medical Technologies in Italy



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Reimbursement and HTA Represent Two Major Market Access Hurdles in Italy

Reimbursement	Acceptance by payers	Stand-alone HTA
Mechanism to pay for technology or medical procedure	**Independent acceptance by payers or national decision-makers**	**Stand-alone health technology assessment**
○ A combination of DRG and global budget reimbursement in hospital settings ○ The National DRG system is rigid with limited structural evolution over time and infrequent updates to tariffs ○ However, regions can change the system (introduce add-on reimbursement and DRG split) and adjust the tariffs ○ Reimbursement incentives for technology adoption vary by region and hospital type	○ Coverage within the national guaranteed basket of services (LEA) has limited relevance for hospital care, as it mainly applies to outpatient services and IVDs	○ National (via AGENAS) and regional/hospital HTA organizations can support decision-making for the adoption of novel technologies

Market Access Landscape Involves Multiple National and Regional Stakeholders

Payers

Local Health Companies (ASLs)
Responsible for organization and financing of health care services. Organized by geographical principle. In some small regions, there is just one ASL (regional payer). Have different names in different regions

Policy-makers

Ministry of Health
Determines the overall strategy of the health care system, defines the guaranteed services to the population (LEA), distributes funds to regional health systems, and monitors the national healthcare system. Manages the national DRG system (structure and tariffs) and list of reimbursable outpatient services with tariffs

Regions
Decide on the introduction of services outside the LEA catalog. May develop other regional policies. Maintain regional DRG systems

State-Regions Conference
A body that was established as a tool for communication between the State and the Regions. Policies brought by the Ministry of Health must be approved by this body in order for the Regions to accept them

Cabina di Regia (Steering Committee for HTA)
Coordination of activities of emerging national HTA program

Decision influencers

National Agency for Regional Healthcare Services (AGENAS)
National organization that performs health technology assessments of individual technologies and develops various analyses on the performance of the healthcare system

National HTA center within the Superior Health Institute (ISS)
Leading HTA body within the emerging concept of national HTA program. Performs HTA for infrastructural projects

National LEA commission
Assesses the suggestions and provides recommendations for the LEA catalog amendments

Regional, local and hospital-based HTA units
Perform evaluation of health technologies to inform decision making about their acceptance. Exist in almost all regions; however, their level of activity significantly differs

Regional Technical Commissions for Medical Devices
Perform assessment and authorization for the use/purchase of medical technologies. Exist in some regions

Regional Economic Disparities Create Structurally Unequal Access to Innovative Devices

Illustrative example showing differences observed across regional economic status

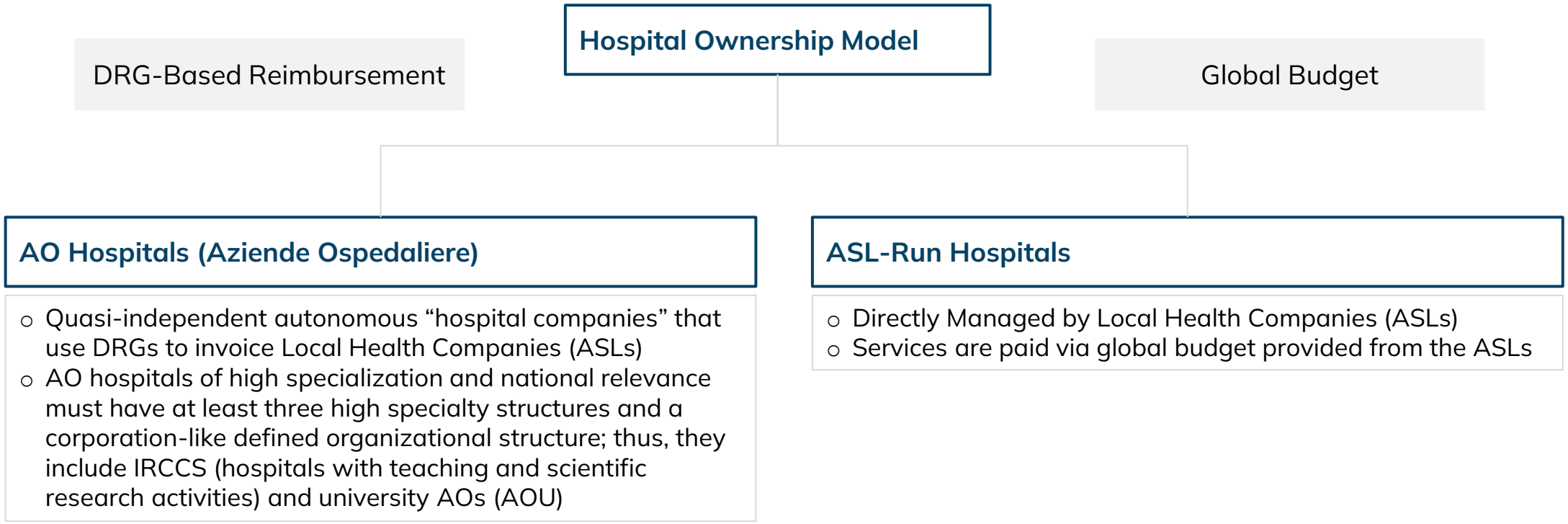
- Regions with high GDP per capita
- Regions with moderately high GDP per capita
- Regions with moderate GDP per capita
- Regions with low GDP per capita

- Italian regions have significant differences in economic status
- The GDP per capita in high-performing northern regions, such as Emilia-Romagna and Lombardy, is more than twice as high as in southern areas, including Calabria, Sicily, and Campania
- It impacts the ability to implement expensive innovative technologies and in vitro diagnostic tests

Payment Models in Italy Vary by Settings, Requiring Different Market Access Strategies

	Hospital and day case settings	Ambulatory settings
Payment model	Diagnosis-related groups / global budget (depending on the ownership status of the hospital) Tariffs are lower for day case procedures vs those for ordinary hospital stays	Fee-for-service model
National level	The Ministry of Health determines the structure of the DRG system and benchmark DRG tariffs	The Ministry of Health determines the list of reimbursable services (listed in the LEA catalog) and their benchmark tariffs
Regional level	Regions develop their own DRG tariffs. Can adjust DRG structure (add-on reimbursement or DRG split)	Regions approve their own reimbursement lists based on the national list. They can change tariffs and introduce additional (extra-LEA) services
Interregional level	The State-Regions Conference approves the DRG tariffs, which are used to reimburse care provided to citizens from other regions	

The Reimbursement Mechanism in Hospital Settings Is Determined by the Hospital Type



The National DRG System Remains Static, Making Regional Pathways the Primary Route for Reimbursement Decisions

Clinical Coding

- All healthcare interventions and diagnoses are coded in compliance with national recommendations. Regional authorities may provide supplementary coding guidelines
- International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM, 2007) is used to code procedures and diagnoses

National DRG system

- Version 24.0 of the Medicare Diagnosis-Related Group (CMS DRG) system from 2007 is in use for acute hospital services
- Specific DRGs are defined by a combination of diagnosis and procedure codes and patient-specific parameters (e.g., age, sex, length of stay, etc.)
- DRGs are meant to cover all variable costs associated with medical procedures, including medical devices, besides capital equipment costs, which are financed by the regions
- DRG tariffs for short stay/day case are lower than those for ordinary stay
- The Ministry of Health is responsible for maintaining the national DRG system, which has seen limited structural updates
- There is no defined procedure to update the classification of DRGs and the related tariffs at the national level. So, it is not merely possible to work on changing the national DRG system

Regional adaptation of DRG structure

- Regions can develop adaptations of the DRG system. They follow the list of the Ministry of Health, but can create sub-DRGs (DRG split) or add-on reimbursement. Regions approve DRG lists annually or every few years
- There is no defined pathway to update the regional DRG system. It includes lobbying through KOLs with the support of the cost analysis data

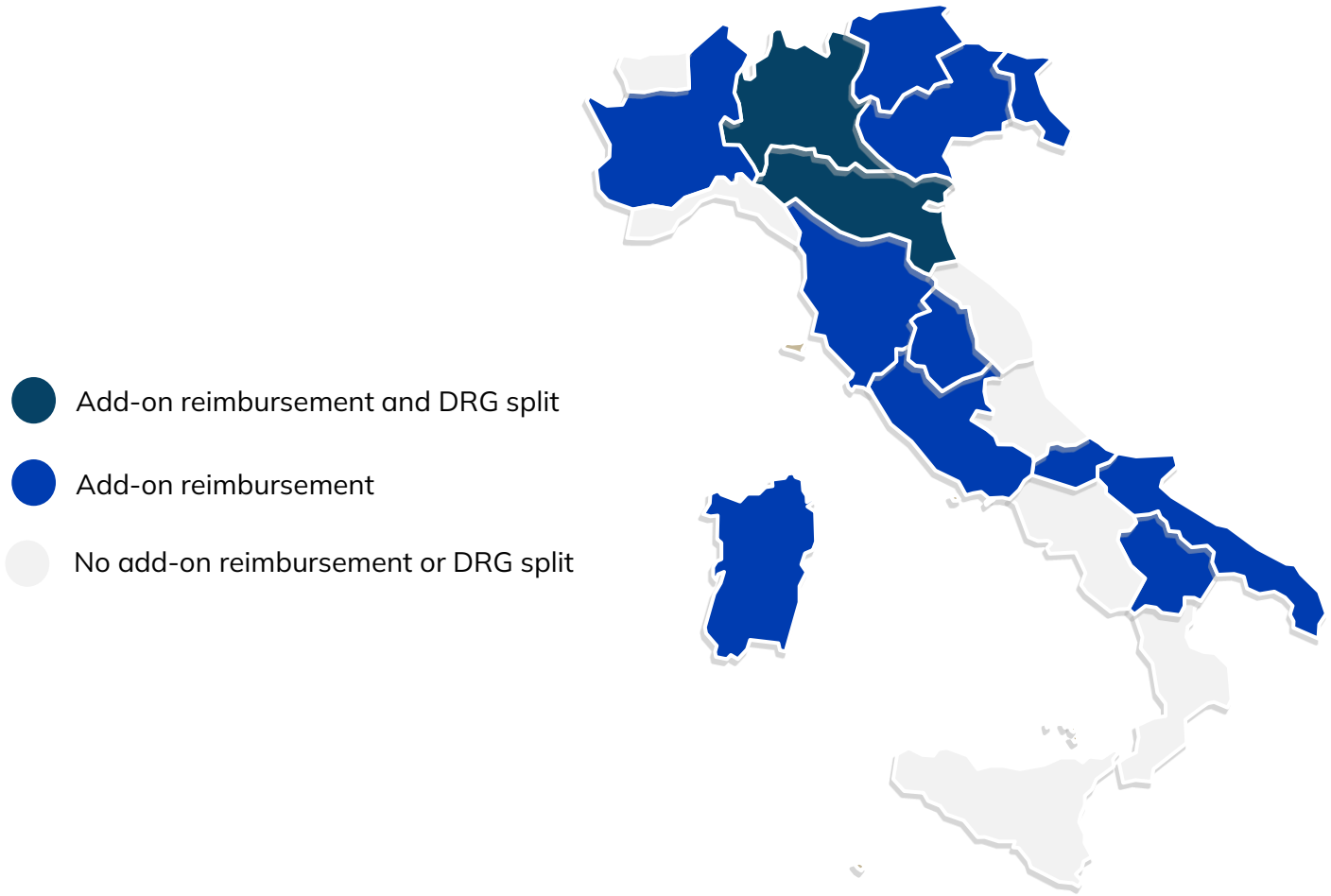
Example of Calculation of DRG

- Example of calculation of reimbursement tariff for therapeutic photopheresis
  - Procedure code: 99.88 “Therapeutic photopheresis”
  - Diagnosis code: 491.8 “Other chronic bronchitis”
  - Age – 50 years
  - Sex – male
  - Discharge status – patient discharged home
  - Length of stay (determines the type of setting): 3 days

  - **Resulting DRG 88: “Chronic obstructive pulmonary disease”**

DRG code and name	Type of DRG	Tariff for ordinary stay (>1day), €	Tariff for short (day case) stay, €	High trim point, days	Daily tariff for excess days of stay, €
88 - Chronic obstructive pulmonary disease	Medical	1,600	170	21	87

Add-On Reimbursement/DRG Split Is Available Only in Selected Regions



- Several regions lack dedicated add-on mechanisms, increasing reliance on DRGs or hospital budgets
- Manufacturers should prioritize regions with established add-on or DRG split frameworks when introducing expensive or complex technologies

Examples of Medical Devices Reported in the SDO4 Form in the Lombardy Region

- Cochlear implant
- Deep brain neurostimulator for Parkinson's disease (including pulse generator)
- Biliary stents in malignant neoplasms of the hepatobiliary system or pancreas
- Esophageal stents in malignant neoplasms of the digestive system
- Vagus Nerve Stimulator for epilepsy (must include pulse generator)
- Robotic surgery kit
- Intravascular lithotripsy (ILVT) catheters
- Catheters for percutaneous ablation of arrhythmogenic foci
- Hip prosthesis - acetabular component, cup
- Coronary drug-eluting stent
- Coated coronary stent
- Single-chamber implantable cardiac defibrillator (including main device and accessories)
- Subcutaneous implantable cardiac defibrillator
- Knee prosthesis - femoral component
- Interatrial or intraventricular prosthesis (umbrella)
- Prosthesis for left lateral auricle occlusion (LLA)
- Percutaneously implanted tricuspid valve
- Rechargeable implantable spinal neurostimulator (including pulse generator)
- Device for mitral valve leaflet anchoring via percutaneous endovascular access
- Ventricular Assist Systems (VAD)
- Glenoid component for shoulder prosthesis
- Coils for the endovascular treatment of cerebral aneurysms
- Intrasaccular devices with woven wire (Woven Endo Bridge)
- Rings for direct mitral valve annuloplasty
- Implantable hemodynamic monitoring system for arteriovenous pressure
- Implantable electrocardiographic monitoring system (loop recorder)
- Vertebral replacement systems
- Microstent for glaucoma drainage
- Intrathecal pump for controlled infusion of drugs
- 3D silicone prosthesis (pectus excavatum)
- Percutaneous cryo-ablation devices
- Sacral neurostimulators (for incontinence)
- Implantable leadless pacemakers

Guaranteed Healthcare Services Are Defined at the National Level, with Limited Update Possibility

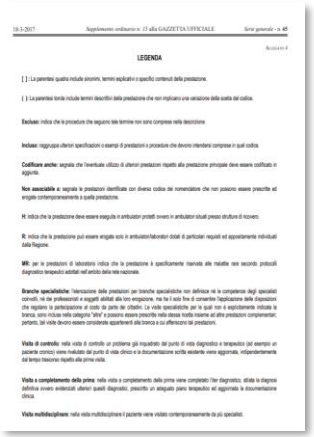
- The document that defines the guaranteed healthcare services to Italian citizens is called the Essential Levels of Care (LEA document). The LEA document is approved by the Parliament, but developed by the Ministry of Health

- Annex 4 of the LEA document (LEA catalog) contains an exhaustive list of outpatient services (including IVD tests) guaranteed to the Italian population. Hospital services are only broadly defined by the LEA document

- Inclusion of services (especially outpatient and IVD tests) in the LEA catalog, in theory, guarantees reimbursement of that service nationwide. It is not very relevant for hospital procedures

- Theoretically, it is possible to introduce changes in the LEA document (and LEA catalog) by making suggestions to the LEA commission of the Ministry of Health
  - The framework for the LEA update has no defined timelines. In practice, revisions to the LEA document occur infrequently and typically require lengthy approval processes involving both institutional and intergovernmental entities. A further update of the LEA document is anticipated in the coming years

- Alternatively, changes in the LEA catalog can be a consequence of the assessment in the national HTA program



LEGENDA

[ ] : La parentesi quadra include sinonimi, termini esplicativi o specifici contenuti della prestazione.

( ) : La parentesi tonda include termini descrittivi della prestazione che non implicano una variazione della scelta del codice.

Escluso: indica che la procedura che seguono tale termine non sono comprese nella descrizione.

Incluso: raggruppa ulteriori specificazioni o esempi di prestazioni o procedure che devono intendersi comprese in quel codice.

Codificare anche: segnala che l'eventuale utilizzo di ulteriori prestazioni rispetto alla prestazione principale deve essere codificato in aggiunta.

Non associabile a: segnala le prestazioni identificate con diverso codice del nomenclatore che non possono essere prescritte ed erogate contemporaneamente a quella prestazione.

H: indica che la prestazione deve essere eseguita in ambulatori protetti ovvero in ambulatori situati presso strutture di ricovero.

R: indica che la prestazione può essere erogata solo in ambulatori/laboratori dotati di particolari requisiti ed appositamente individuati dalla Regione.

MR: per le prestazioni di laboratorio indica che la prestazione è specificamente marcata alle malattie rare secondo protocolli diagnostici terapeutici adottati nell'ambito della rete nazionale.

Branche specialistiche: l'elencazione delle prestazioni per branche specialistiche non definisce né la competenza degli specialisti coinvolti, né dei professionisti e soggetti abilitati alla loro erogazione, ma fa il solo fine di consentire l'applicazione delle disposizioni che regolano la partecipazione al costo da parte dei cittadini. La visita specialistica per la quale non è esplicitamente indicata la branca, sono incluse nella categoria "altra" e possono essere prescritte nella stessa ricetta insieme ad altre prestazioni comprensibili; pertanto, tali visite devono essere considerate appartenenti alla branca a cui afferiscono tali prestazioni.

Visita di controllo: nella visita di controllo un problema già inquadrato dal punto di vista diagnostico e terapeutico (ad esempio un paziente cronico) viene rivalutato dal punto di vista clinico e la documentazione scritta esistente viene aggiornata, indipendentemente dal tempo trascorso rispetto alla prima visita.

Visita a completamento della prima: nella visita a completamento della prima viene completato l'iter diagnostico, stilata la diagnosi definitiva ovvero evidenziati ulteriori quesiti diagnostici, prescritto un adeguato piano terapeutico ed aggiornata la documentazione clinica.

Visita multidisciplinare: nella visita multidisciplinare il paziente viene visitato contemporaneamente da più specialisti.

Market Access in Outpatient Settings Combines National Coverage and Regional Reimbursement Pathways

National Coverage via Essential Levels of Care (LEA)

- In Italy, outpatient services are reimbursed via a fee-for-service mechanism
- The document defining guaranteed healthcare services for Italian citizens is the Essential Levels of Care (LEA)
- Annex 4 (LEA catalog) contains an exhaustive list of outpatient services, including IVD tests, guaranteed to the Italian population
- Inclusion of a service in the LEA catalog shall, in theory, guarantee reimbursement nationwide
- Inclusion of services in the LEA catalog and updates to the LEA document are subject to lengthy institutional approval processes, involving the State–Regions Conference, before final implementation
- The framework for updating the LEA and its catalog exists, but revisions occur infrequently and require multi-level institutional approval

Regional Adoption and Reimbursement

- Regions maintain regional nomenclatures of outpatient services based on the national LEA catalog
- Regions may introduce additional services beyond the LEA catalog
- Regions freely determine reimbursement tariffs for regional services
- National tariffs serve as a benchmark, but are not binding
- Positive recommendations by the national (AGENAS), regional, or hospital HTA bodies can support the adoption of the new IVDs by healthcare providers

High-Cost Technologies May Trigger Regional Coverage Decisions in Some Regions

- For hospital procedures and devices, coverage decisions on the regional level sometimes occur
  - Coverage decisions are not always required; typically, they are developed only for high-cost procedures and devices, when specific guidance for the use of the method, as well as monitoring of the performance, is required
- Regional Technical and Device Commissions play a key role in regional coverage decision-making
  - However, these commissions do not exist in all regions. In regions where these do not exist, HTA reports of regional HTA bodies play a similar role (more details in the next section)
- Regional Technical and Device Commissions can use the HTA methodology, although they are not HTA bodies
- Typically, the tasks of these Commissions include the evaluation of innovative medical technologies, developing guidelines for adequate use and implementation of innovative technologies, but also the necessary (minimum) requirements for the introduction of innovative technologies in the hospitals

National and Regional HTAs Play an Active Advisory Role in Market Access

National level

- National HTA body - **National Agency for Regional Health Systems (AGENAS)** conducts evaluations on topics of high importance for public health (regular HTAs and horizon scanning)
- The **National HTA program for medical devices (PNHTA)** is currently active and supports multi-level healthcare decision-making

- Impacts national and regional decision-making levels
- Recommendations are disseminated to the National Commission for the Essential Levels of Care (LEA) and regional directorates that will circulate them across hospitals and regional procurement units

Regional and hospital-based levels

- In addition to the national HTA, there is a broad network of regional and hospital-based HTAs in Italy
- However, in recent years, Lombardy and Tuscany have been the only regions with an active HTA framework
- In some regions, there are Technical Committees for Medical Devices, which are responsible for the approval of innovative technologies for use. They can use the HTA methodology, but they are not HTA bodies

- Impacts regional adoption
- Can be part of the decisions to create a regional payment mechanism for innovative technology or to adopt a novel technology at the regional or hospital level

There are two other HTA organizations in Italy, SIHTA (Italian Society for HTA) and RIHTA (Italian HTA Network), but they both have only a networking/collaborating role

Tuscany Regional HTA Body (C-HTA) Is the Most Active Regional HTA Organization in Italy

Devices for which an HTA is required

- New and emerging technologies that have not yet been adopted in the Tuscan Regional Health System, and which are generally in the market launch or initial distribution phase
- Widespread or obsolete technologies if a change in the clinical indication or use is noted, or there is a need for the re-evaluation of the appropriate use
- Innovative medical devices prior to purchase

Types of HTA documents

- Rapid Review, Mini HTA, Rapid HTA, Full HTA, and Adapted HTA. Although in practice, only Rapid HTA reviews are published
- Over time, a large and growing number of HTA reports (over 200) have been produced, making Tuscany the most active regional HTA body for medical technologies in Italy. Other regions are not very active with HTA in recent years

Application process

- Various stakeholders (including industry) are allowed to request an assessment of new technologies by submitting a form. In reality, all of the published rapid HTA reviews are a consequence of a request for the purchase of a new technology initiated by physicians working in Tuscan hospitals
- Institutions, private companies (industry), and patient associations can also submit a request for a hearing, in which they can present new technologies to the regional healthcare authorities

HTA Recommendations

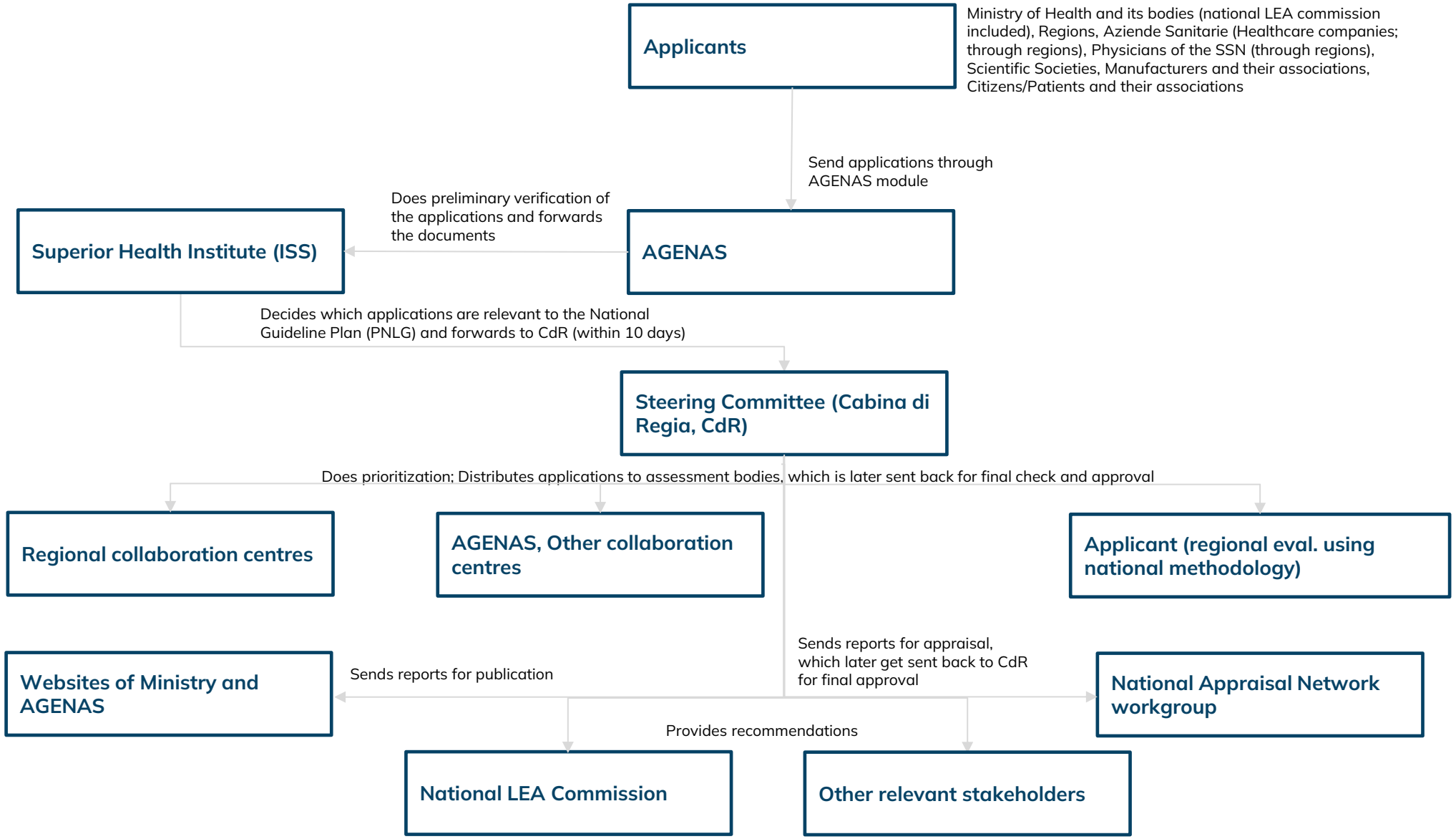
- Introduction of the device is favorable. If an HTA report issues a favorable opinion, the new medical device is generally introduced into the health system and purchased by healthcare providers
- Introduction of the device is possible only with a collection of evidence on real effectiveness and efficiency (managed introduction)
- Use of the device only in a research context to produce further evidence
- The introduction of the device is not favorable

In Tuscany, the Commission for the Assessment of Health Technologies and Investments (C-HTA) sets regional priorities, evaluates new investments and technologies, supports procurement decisions, and advises regional decision-makers on the efficient use of resources. Furthermore, C-HTA makes final recommendations to the regional decision-makers regarding the purchase of new technologies based on the evaluations developed by the Operating Center

An Active National HTA Program Guides Device Adoption Decision

- National HTA program for medical devices (Programma Nazionale di Health Technology Assessment, PNHTA) was launched in September 2017
- Agreement on the national HTA program for medical devices has been reached between central and regional authorities. The leading body is the Cabina di Regia per l'HTA, a national steering committee coordinated by the Ministry of Health and involving the Ministry of Health, Regions, the national agency for regional healthcare (AGENAS), and the Italian Medicines Agency (AIFA)
- The steering committee (CdR) coordinates activities aimed at the production of the following deliverables:
  - List of technologies notified for evaluation
  - List of technologies prioritized for assessment
  - HTA reports for prioritized technologies
  - Recommendations for appropriate use within the healthcare system (appraisal reports)
  - Working plan for the coordination of the activities related to the national HTA programme
- The deliverables will be disseminated among all the decisional levels of the national healthcare system, from the national commission for the essential level of care (Commissione Nazionale LEA) to the regional directorates that will circulate them across hospitals and regional procurement units
- The national HTA program for medical devices has become operational and is now actively producing assessments
  - Initial evaluations have focused on complex and high-impact technologies, demonstrating the program's role in supporting evidence-based decision-making at the national level
- The program also operates a formal prioritisation mechanism that identifies medical technology areas for assessment. Priority topics typically reflect areas of significant clinical impact and innovation. The list of prioritised technologies is updated periodically, providing forward visibility on assessment focus areas and helping stakeholders anticipate upcoming HTA activities

National HTA Program Uses a Structured Multi-Stakeholder Process for Application, Assessment, and Recommendations



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